UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,905	04/24/2000	TOHRU TANI	FJN-077	7282

7590 06/03/2003

TESTA HURWITZ & THIBEAULT
HIGH STREET TOWER
125 HIGH STREET
BOSTON, MA 02110

EXAMINER
DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	22

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/423,905	Applicant(s) Tani et al
	Examiner Patricia A. Duffy	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 12, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-5, 7-10, 13-16, and 18-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-5, 7-10, 13-16, and 18-21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The after final amendment of 3-12-03 has been entered into the record. Claims 2-5, 7-10, 13-16, and 18-21 are pending.

2. The finality of the rejection of the last Office action is withdrawn in view of the new rejections set forth herein based on Art of Record.

New Rejections

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2-5, 7-10, 13-16 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticiapted by Masunaga et al, (U.S. Patent No. 5,714,461, issued February 3, 1998).

Claims 2-5 and 7-10 are drawn to reducing sepsis associated lethality by administering tumor cytotoxic factor II (TCF-II) to a mammal "at risk" of sepsis-associated lethality in an amount effective to reduce sepsis associated lethality.

Claims 13-16 and 18-21 are drawn to reducing bacterial translocation in a mammal comprising administering tumor cytotoxic factor II (TCF-II) to a mammal "at risk" of bacterial transloaction in the intestine in an amount effective to reduce vacterial translocation.

Masunaga et al teach the administration of tumor cytotoxic factor II (TCF-II) to ameloriate disseminated intravascular coagulation (DIC) wherein the basal disease causing the DIC is sepsis, tumors, infectious disease etc (paragraph bridging column 1-2). Masunaga et al teach administration of purified TCF-II (column 3, lines 24-34) or recombinant TCF-II (Column 5, Example 2), in a pharmecutical composition that has a pH conditioner in a buffer (PBS, pH 7.0) and a stabilizer (horse serum albumin) (see columns 5-6 and as such meets the limitation of claims 8 and 19). The pharmaceutical compositions comprising TCF-II were administered in amount of about 100-30,000 ug/Kg (0.1 mg-30 mg/Kg) or about 500-3000 ug/Kg (0.5 -3 mg/Kg) see column 3, lines 47-54) and as such meets the limitations of claims 9, 10, 20 and 21). Masunaga et al teach that TCF-II may be administered by intravenous, intraarterial, intramuscular or subcutaneous injection (see polumn 3, lines 33-38) and as such meets the limitaiton of claims (3 and 14).

As to claims 2-5 and 7-10, the claims require that the composition of TCF-II be administered to mammals "at risk of sepsis associated lethality" and therfore the mammals having DIC associated with sepsis of Masunaga et al meet this limitation. Since, the dosages of the TCF-II are the same and the TCF-II is administered to the same "at risk" population of mammals, the method of administering the TCF-II of the prior art would inherently perform the function of reducing lethality.

As to claims 13-16 and 18-21, the claims require that the composition of TCF-II be administered to mammals "at risk of LPS-induced bacterial translocation in the intestine" and therfore since all mammals normall have bacteria present in the intestine, all mammals are therefore "at risk of LPS-bacterial translocation in the intestine" and the treatment of mammals having DIC associated with any disease including sepsis as taught by Masunaga et al meet this claimed limitation. Since the dosages of the TCF-II are the same and the

TCF-II is administered to the same "at risk" population of mammals (i.e all mammals because all mammals normally have LPS-containing bacteria in the intestine), the method of administering the TCF-II of the prior art would inherently perform the function of reducing LPS-mediate bacterial translocation. Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); Bristol-Myers Squibb Co. v. Ben Venue Laboratories Inc. 58 USPQ2d 1508 (CAFC 2001).

Citation of Relevant Art

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Davis et al (Microbiology, third Edition, 1980, Harper and Row Inc.) pages 82, 646-647 teach that lipopolysaccharide (LPS) is innate to the outermembrane of Gram Negative organisms (page 82) and that Gram Negative organisms such as Escherichia coli are normal flora of the vetebrate gut (see page 646, column 1, first paragraph and page 647, column 1, Table 31-1).

Status of Claims

6. No claims are allowed.

7. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
May 23, 2003

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600